Written Statement of James A. Dahl

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Mr. Chairman and members of the committee, thank you for the opportunity to testify today on this important issue. I appear before you as a private citizen, but one with considerable knowledge on this topic. In my remarks today and in my submission for the record I hope to represent the interests and opinions of the 185 special agents of the FDA Office of Criminal Investigations who are the true experts on counterfeit drugs and related pharmaceutical crime.

I would like to first comment on the scope of the problem. Too often some tend to isolate the issue of counterfeit drugs from the broader but related range of pharmaceutical crime which includes wholesale and street level diversion schemes, illicit internet sales, and an enormous influx of foreign small parcel shipments containing unapproved, misbranded, adulterated, and/or counterfeit drugs (or components thereof). All of these issues are related, and all present significant public health concerns.

That said, I believe the most serious threat to unsuspecting patients today is the corruption of what should be, but is not, a highly regulated pharmaceutical supply chain. In fact our drug distribution network is being corrupted through the introduction of counterfeit and diverted prescription drug products. As I try to recall the myriad of counterfeit drug cases over the years I cannot think of a single case in which counterfeit products entered the "legitimate" marketplace without the aid of an existing diversion infrastructure. Couple that with the fact these illicit diversion networks not only distribute drugs obtained by fraud, but also traffic in drugs which are misbranded, stolen, expired, previously dispensed, illegally re-packaged, or otherwise suspect, and you can see we have a huge problem on our hands – a problem that endangers every American consumer.

The availability of drugs from unregulated and virtually anonymous foreign and at times domestic internet sites also presents an unacceptable level of risk. Small foreign originating parcels arriving via commercial carriers and the mail give criminal distribution organizations a smooth flow of inventory, with little chance of significant interruption, and even less risk of criminal prosecution.

I do want to praise those states that, despite a lack of any significant federal leadership on this issue, have moved forward with new laws to regulate wholesale drug distribution. In particular I applaud the efforts of the NABP and its Model Act, which promotes the more secure wholesale distribution of prescription drugs.

The problems described above become even more alarming when one considers something that OCI has always said - drugs are at least as susceptible to terrorist attack as foods. Yet the resources directed to food security within the FDA and throughout government are significantly disproportionate from those devoted to pharmaceuticals. Existing criminal infrastructures along with others continuing to be formed and the inherent weakness of our current distribution system certainly present opportunities for delivery of select agents to targeted patient populations. Such action could have a potentially catastrophic impact on public health and consumer confidence. Moreover, the huge illegal profits enjoyed by pharmaceutical crime organizations can be used to provide material support to terrorist organizations. We must increase the level of vigilance and resources in vulnerability analysis, threat assessment and criminal investigative response if we are to prevent such catastrophic events.

While the FDA and others primarily focus on public health awareness, suggestions for others, voluntary compliance, and published studies without formally calling for new legislation, the agency neglects some available regulatory options and an enhanced criminal enforcement approach that could provide better results.

So what should we do?

First, fully implement the PDMA regulations requiring a pedigree on wholesale transactions of prescription drugs (21 CFR 203.50). Although the underlying law has some loopholes that need attention, the pedigree regulations as currently written would help control unscrupulous wholesalers and would provide evidence and information useful to OCI in its criminal investigations. OCI has recommended full implementation of the pedigree rule ever since it was originally proposed in 1999. It is now time for Congress and the American public to demand that the stay on these regulations be lifted.

Second, enact new legislation that would assist OCI and others in their criminal investigations. I'd like to highlight just a few of the changes needed:

- Administrative subpoena authority for use by OCI agents in their felony investigations needs to be authorized. This is a very effective tool commonly used by a variety of other agencies including the IRS, Bureau of Immigration and Customs Enforcement (ICE), and every Inspector General in the federal government. OCI desperately needs to have such a tool at its disposal; a tool that would call only for the production of documentary evidence (and not testimony). If a HUD OIG agent can use an administrative subpoena to collect evidence of false statements on a mortgage application, I am sure the American public would agree that an OCI special agent should be able to use a similar tool to gather evidence concerning criminal organizations that would deliver substandard or counterfeit drugs to an unsuspecting patient in a hospital.
- Title 18 of the U.S. Code needs to be amended to make Food Drug and Cosmetic Act felonies predicate offenses under the racketeering statutes (18 USC 1961) and specified unlawful activities for money laundering (18 USC 1956). Most FD&C Act

offenses are committed for economic gain. Like so many other federal agencies OCI needs these tools to effectively attack the increasingly sophisticated criminal enterprises that put the public health at risk.

- In addition, Section 982 of Title 18 United States Code needs to be amended to allow upon conviction the direct forfeiture of the gross proceeds from felony violations of the FD&C Act. This not only helps punish the defendant for his illegal actions, but also aids in effectively dismantling the criminal enterprise that could otherwise continue to prey upon the public.
- Title 21 of the U.S. Code needs to be amended to provide for higher maximum penalties for felony violations of the FD&C Act. I would suggest that penalties be linked to the actual or potential harm caused by the illegal conduct in a manner similar to that provided under the Federal Anti-Tampering Act (18 USC 1365). It does not make sense that a person risks up to ten years in prison for counterfeiting a registered trademark (18 USC 2320), but only three years for counterfeiting a drug. On a related note OCI and the FDA Office of Chief Counsel have been working for several years to improve the sentencing guidelines for FD&C Act offenses. If new legislation is enacted it should include a provision calling for the U.S. Sentencing Commission to immediately consider increases in the sentencing guidelines for all FD&C Act felonies.
- Title 21 of the U.S. Code also needs to be amended to modernize and improve enforcement generally. For instance, the definition of what constitutes a counterfeit drug needs to be broadened; a provision making the "attempted" commission of FD&C Act felonies a crime needs to be enacted; a "sting" provision needs to be included to improve the effectiveness of undercover operations; and seizure laws at ports of entry need to be streamlined to allow the Bureau of Customs and Border Protection (CBP) and the FDA to efficiently and effectively seize and dispose of violative products.

My third suggestion for dealing with counterfeit drugs and related pharmaceutical crime is one of resources. OCI's operational budget (less salaries, benefits and real estate expenses) for FY 2005 was a paltry $3.96 million. Yet at any given time during fiscal year 2005 OCI had an inventory of approximately 800 to 900 open and active investigations, many addressing the priority issues spoken of today, along with others involving such diverse and important matters as consumer product tampering, drug application fraud, medical device crimes, false statements to the agency, illegal trade in human tissue for transplant, adulterated biologics, etc. Yet it appears to me that OCI has become a victim of its own success. I believe OCI provides the agency with its biggest bang for the buck, yet it is again being asked to do more with less. OCI simply needs more operational funding and more people to adequately address the increasingly complex and sophisticated criminal cases that appear on the horizon each day. For instance, an influx of appropriate resources through supplemental appropriation and/or re-deployment of existing FDA/HHS resources would allow OCI:

- To conduct a more thorough strategic and tactical analysis of the counterfeit drug, internet distribution, and drug importation problems,
- To place investigative analysts in field offices where they could directly assist working agents,

- To expand an international strategy that includes active participation in various law-enforcement conferences, training and meetings around the world; and to develop effective law enforcement relationships and strategies so that more prosecutions and preventative actions could be brought in foreign countries and in the U.S.
- To initiate a more proactive approach to addressing pharmaceutical crimes without a decrease in investigative capability
- To hire, train and deploy additional agents and support personnel throughout the country to more effectively confront the criminals of the 21st century.

Resources are always a sensitive issue, but the time has come that we must confront this crime problem with real solutions. As a start, a mere million dollars in operational funding along with a couple dozen fully funded FTEs would go a long way to addressing these issues.

In conclusion, I would like to publicly compliment the men and women of OCI and the United States Attorneys Offices around the country for their continued dedication and resourcefulness in investigating and prosecuting pharmaceutical crime. Every day they are out there doing interviews, recovering evidence, conducting surveillance, serving search warrants, seeking indictments, making arrests, testifying in court, and much much more. Without their continued good work this country would be facing even greater problems. I also believe we need to remember that FDA's overall mission is extremely important and at times overwhelmingly complex. But the problem of criminal attacks against the pharmaceuticals we all rely on cannot be solved with a status quo Office of Criminal Investigations. The FDA must confront drug counterfeiting and pharmaceutical crime as a law enforcement problem. It must continue to seek and seriously consider advice from the true experts within and outside the agency, and adopt a political will to provide law enforcement with the tools and resources needed for a solution.